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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,174	11/07/2001	Nabil Hanna	P 0280732 2000-30-0261 VUS	4956
909	7590	04/21/2006	EXAMINER YU, MISOOK	
PILLSBURY WINTHROP SHAW PITTMAN, LLP P.O. BOX 10500 MCLEAN, VA 22102			ART UNIT 1642	
DATE MAILED: 04/21/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/986,174	<b>Applicant(s)</b> HANNA, NABIL	
	<b>Examiner</b> MISOOK YU, Ph.D.	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16, 17 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16, 17, 23-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/25/2006 has been entered.

Claims 16, 17, and 23-27 are pending and examined on merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This Office action contains new grounds of rejection.

### ***Priority***

Acknowledgment is made of applicant's amendment on 1/25/2006 to the first line of the specification filed

### ***Claim Rejections - 35 USC § 112, Maintained***

Claim 25 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the engineered antibody fragment whose sequence has been published, does not reasonably provide enablement for the specifically recited antibodies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant argues that the CDR region of the antibody has been published, therefore the deposit is not required.

This argument has been fully considered but found unpersuasive because the full scope of the claim requires not only the CDR regions of antibody but also requires the monoclonal antibody produced by the hybridoma.

***Claim Rejections - 35 USC § 103***

The rejection of claims 16, 17, and 23-27 under 35 U.S.C. 103(a) as being unpatentable over Demidem et al., Cancer Biother Radiopharm., June 1997, vol. 12, pages 177-186 in view of Hagenbeek et al., J Clin Oncol., January 1998, vol. 16 pages 41-47, further in view of Reff et al., 1994, Blood, vol. 83, pages 435-445 is **withdrawn**.

Claims 16, 17, and 23-27 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al., July 2000, Clinical Cancer Research, vol. 6, pages 2644-2652 in view of Taji et al., Jpn. J. Cancer Res., July 1998, vol. 89, pages 748-756.

Claims 16, 17, and 23-27 are drawn to method of enhancing apoptosis of lymphoma B cells using an immunoconjugate comprising an anti-CD20 antibody or a fragment thereof fused at its carboxy terminus to IFN-alpha-2a.

Applicant argues that the synergy in Davis reference is not statistically significant, and require further clinical trials, and the two active agents are not administered on the same day, and Taji reference does not overcome the defect in the defects in Davis reference.

These arguments have been fully considered but found unpersuasive for the following reasons.

Davis teaches at page 2645, right column that an anti-CD20 antibody (i.e., Rituximab) and IFN had synergistic effect on preclinical trials, therefore the reference motivates one of skill in the art to combine the two active agents. Thus, Davis, et al., do not teach whether the good result is from enhancing apoptosis of the B lymphoma cells. Taji et al., teach that an anti-CD20 antibody enhances apoptosis of B lymphoma cells (note the title and also Fig. 4 at page 752). As for the agents not being administered on the same day, it is well within the level of ordinary skill in the art to recognize that administering fusion of anti-CD antibody linked to IFN-alpha-2a would minimize applicant's discomfort by injecting once vs. twice.

Therefore it would have been obvious to one of the ordinary skill in the art to make and use an anti-CD20 antibody or a fragment thereof is fused at its carboxy terminus to IFN-alpha-2a in the method of enhancing apoptosis in B cell lymphoma, thereby treating the lymphoma with a reasonable expectation of success since how to make recombinant interferon alfa-2a, and how to construct anti-CD20 antibody expression construct had been well known in the art before the effective filing date of the instant application. One of an ordinary skill would have been motivated to make the fusion to minimize the painful injections by giving one fusion protein instead of two separate injections, and/or purifying one protein instead of two proteins, thus reducing cost and saving time.

***The Following Are New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 contains the trademark/trade name. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the material and, accordingly, the identification/description is indefinite.

No claim is allowed.

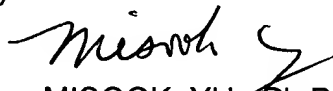
Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-

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272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
MISOOK YU, Ph.D.  
Primary Examiner  
Art Unit 1642